

LISTING & STATUS OF ELAB RECOMMENDATIONS

4/29/99 version

Priorities Defined:

HIGH - activity is an urgent matter; an ELAB member has been assigned to monitor progress on the recommendation

MEDIUM - activity is of importance to ELAB; ELAB will monitor progress periodically

INACTIVE - activity either has been dealt with under another recommendation or is no longer applicable

COMPLETE - recommendation has been addressed or acted upon by ELAB or another organization

Rec. #	Date of Rec.	Recommendation	Notes	Action	ELAB Priority
1	2/6/97	The GLP Subcommittee will present a final report and recommendations at the next ELAB meeting in July, 1997.		ELAB completed report. Awaiting response from EPA EMMC Policy Council. Letter received from EPA/OECA 4/15/99; forwarded letter to NELAC.	COMPLETE
2A	2/6/97	The issue of how to define the basis for NELAC accreditation is of concern to the laboratory community and should continue to be addressed jointly by the NELAC Committees on Proficiency Testing and Program Policy and Structure. ELAB participation in the effort will be the responsibility of Mr. Coyner and Ms. Moore, who are members of the Proficiency Testing and Program Policy and Structure Committees, respectively.		Recommendation remains open. Awaiting action from NELAC PT and PPS committees and ELAB members.	INACTIVE

2B	2/6/97	ELAB recommends to EMMC and the NELAC Board of Directors, regarding proficiency testing, that the goal of the NELAC PT program should be to provide full-volume, real-world samples, keeping in mind considerations of practicality and cost.		Recommendation remains open. Awaiting action from NELAC Board and EMMC Policy Council.	INACTIVE
2C	2/6/97	ELAB recommends to EMMC and the NELAC Board of Directors, regarding proficiency testing, that the USEPA serve as the oversight body for the PT program, with the necessary resources and commitment to improve the current system. Alternatively, ELAB recommends that the oversight body be another government organization and that steps be taken to ensure a smooth transition.		Completed - NIST to serve as PTOB.	COMPLETE
3	2/6/97	ELAB will recommend to the NELAC Board of Directors that the Program Policy and Structure Committee address the issue of how to recognize an appropriate role for Native American Tribal Nations in NELAC.		Recommendation remains open. Awaiting action from NELAC Board and PPS committee.	MEDIUM

4	2/6/97	With regard to the role of private-sector accrediting bodies in NELAC, ELAB will recommend to the NELAC Board of Directors that the NELAC national database include publicly available information describing the functions performed by individual private organizations for specific State programs.		Recommendation remains open. Awaiting action from NELAC Board.	HIGH (Sandra Wroblewski and Bill Kavanagh assigned)
5A	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that USEPA's programs and Regions and the States work to implement PBMS consistently.		Recommendation remains open. Awaiting action from NELAC Board and EMMC Policy Council.	HIGH (Jerry Parr assigned)
5B	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that training in implementation of PBMS is needed for State laboratory inspectors.		Recommendation remains open. Awaiting action from NELAC Board and EMMC PC.	HIGH (Jerry Parr assigned)
5C	2/6/97	ELAB recommends to the EMMC and the NELAC Board of Directors that a representative from the EMMC Work Group on PBMS work with the ELAB PBMS Subcommittee in the future.		L. Williams, L. Autry, and B. Runyon, all from EPA, participated on the PBMS Workgroup.	COMPLETED

6	7/28/97	ELAB recommends that EPA prepare a working set of PT sample design criteria which meet Program Office requirements to be used by the Proficiency Testing Oversight Body (PTOB) to include, at a minimum, concentration, interferences, media.	NELAC is working with EPA/EMMC to develop specifications for proficiency testing (PT) sample design criteria for use by the Proficiency Testing Oversight Body (PTOB). EPA is also working with NIST to develop a draft of the standard. The draft is currently awaiting response from EPA.	Recommendation remains open. Criteria have been developed for the Water Pollution (WP) and Water Supply (WS) samples. ELAB wishes to reinforce that the recommendation is still important. Awaiting action from EPA Program Offices for criteria other than WP and WS. Will be addressed under #39.	INACTIVE
7	7/28/97	ELAB recommends that NELAC/NIST/EPA develop a protocol which can be used by the PTOB, through review and analysis of data, to assure program equivalence among PT providers. (See attached paper by Dan Tholen for starting point.) ELAB further recommends that this protocol be finalized as soon as possible to ensure the integrity of this program.	The NELAC PT committee has worked with NIST and EPA to produce a draft standard for PTOB to assure equivalence among PT providers. An overview of the draft document, Handbook 150-xx, was given by NIST in the NIST Open Meeting on the morning of January 16, 1998. NIST reviewed Handbook 150-xx and requested public comments by March 15, 1998. Members of the ELAB were impressed with the draft document and the cooperation with NIST and EPA.	Completed. ELAB sent a letter to EPA and NIST complimenting them on their work to date on developing Handbook 150-XX.	COMPLETE

8	7/28/97	ELAB recommends to NELAC that the periodic PT studies occur at fixed times throughout the year. ELAB further recommends that initial and remedial PT samples may be obtained outside this schedule.	ELAB has formerly recommended to NELAC that periodic PT studies be conducted at fixed times throughout the year. The problems created by labs not being able to receive or reinstate accreditation due to scheduling were discussed. ELAB is concerned about the effect of having only two opportunities per year for obtaining PT samples, will have on the accreditation process, both initial and remedial. ELAB recommends that NELAC ensure that the PT system not delay the laboratory accreditation process by more than thirty days.	PT standards have been revised to indicate that accrediting authority may set the schedule. Remedial samples may be obtained	COMPLETE
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9A	7/28/97	ELAB recommends that the long range goal of NELAC be to develop a consistent approach to both scope of accreditation and PT program sample design, which recognizes the needs of the laboratories, the primary accrediting authorities, and the Agency, particularly with regard to performance based methods, similar technologies, and analytical capabilities.	The goal to develop a consistent scope of accreditation and PT programs has been endorsed by the NELAC PT Committee. ELAB discussed the need for the scope of accreditation and PT programs to address performance based measurement systems (PBMS), similar technologies, and analytical capabilities. It was suggested since PBMS is still under development by EPA, NELAC should monitor progress in this program but avoid any delays in the implementation of the NELAC PT program.	Recommendation remains open. Awaiting action from NELAC PT and PPS committees. New ELAB workgroup addressing scope of accreditation issue.	INACTIVE
9B	7/28/97	ELAB recommends that the PTOB, during implementation of the PT program, require that each PT provider record and report PT results to both the accrediting authority and the PTOB on a method basis, by matrix and analyte.	NELAC is awaiting EPA specifications for reporting by method, matrix, and analyte. ELAB will recommend that the Proficiency Testing Oversight Body (PTOB) require that each PT provider record and report PT results to both the accrediting authority and to the PTOB to meet the EPA specifications.	Completed. The PT committee's proposed standards for program/matrix/analyte was adopted by NELAC.	COMPLETE

9C	7/28/97	ELAB recommends to NELAC that a task group monitor the impact on implementation of the discrepancy between PT program design and the scope of accreditation.		Recommendation remains open. Awaiting action from NELAC once program is operational.	INACTIVE
10	7/28/97	ELAB recommends that there is consistency between NELAC Standards and the EPA's PT Externalization program.	NELAC is working closely with EPA and EMMC to insure that NELAC standards are consistent with EPA's PT externalization program. A PT Committee meeting with EMMC in September 1998 indicated close cooperation in developing consistent PT standards.	Completed.	COMPLETE
11	7/28/97	ELAB recommends that the proposed PT standards (including the Appendices) be adopted as presented.	The recommendation to adopt the proposed PT standards has been accomplished.	Completed.	COMPLETE

12	7/28/97	<p>ELAB recommends to NELAC that the GLP decisions and the NELAC timeline be decoupled.</p> <p>ELAB further recommends that the GLP subcommittee report to the ELAB at the Interim Meeting with three options including a) status quo; b) Options 1 + 3 + 5; and c) lab accreditation.</p> <p>ELAB further recommends that ISO Guide 25 be explicitly considered to understand the value it offers to the GLP process.</p> <p>ELAB further recommends that the NELAC process be evaluated to identify the value added, if any. EPA will provide language to clarify that the NELAC Constitution and Bylaws reflect that decision-making and implementation of the GLP Program will continue as an exclusively federal program.</p> <p>The goal of this activity is to provide information to OECA and OPPTS management for a decision regarding the direction of the GLP program.</p>	Addressed in the GLP report.	Completed. GLP report has been forwarded to EPA - awaiting response from EMMC Policy Council.	COMPLETE
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13	7/28/97	ELAB recommends that before EPA promulgates a regulation, it must demonstrate and document that MQOs are achievable using available measurement technology. Recommendations modified to: ELAB recommends that before EPA publishes a method, whether in regulation or guidance, the method must be demonstrated reliable for its stated use.	This recommendation was reconsidered and determined to need modification (see above). This issue was brought to the attention of the EPA Acting Deputy Administrator Peter Robertson on March 9, 1999, at which time he agreed to pursue this issue with the EMMC Policy Council.	Recommendation remains open. Awaiting response from Deputy Administrator.	HIGH (Jerry Parr assigned)
14	7/28/97	ELAB recommends that EPA demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended, that is, don't publish a regulation without a method that works. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.)	The Board voted to include an additional clarifying phrase to the recommendation	Recommendation remains open. Awaiting response from EMMC Policy Council.	HIGH (Jerry Parr assigned)
15	7/28/97	ELAB recommends that EPA consider the following remaining important unresolved issues: <ul style="list-style-type: none"> - PB Measurement System <u>vs.</u> PB Method - Sample matrix - Method Validation - Method Compliance - Interlaboratory Comparability - Cost - Laboratory Client Relationship 		Recommendation has been superseded by final report of the PBMS Work Group.	HIGH (Jerry Parr assigned)

16	7/28/97	ELAB recommends to NELAC that the initial approval of accrediting authorities should occur simultaneously.		Completed. The NELAC Transition Committee has implemented this recommendation.	COMPLETE
17	7/28/97	ELAB recommends to NELAC that the first round of NELAC accreditation of laboratories by accrediting authorities should also occur simultaneously.		The NELAC Transition Committee has implemented this recommendation.	COMPLETE
18	7/28/97	ELAB recommends to NELAC that prior to the designation of approved proficiency test (PT) sample providers as required by Chapter 2, accredited labs should be allowed to continue using existing PT sample providers. However, in the interim, frequency of PT sample analysis as required by Chapter 2 must be met.		Completed. The NELAC Transition Committee has implemented this recommendation. The PT committee has modified the PT chapter to accommodate this recommendation.	COMPLETE
19	7/28/97	ELAB recommends to NELAC that Chapter 6 be further defined regarding Accrediting Authority recognition of States to address the conflict of interest between public and private sector labs, with respect to a State laboratory conducting routine environmental testing analyses. Further definition will include the specific guidance to avoid conflict of interest for an above stated Accrediting Authority.	The NELAC Accrediting Authority Committee has implemented this recommendation. At NELAC IV further complaints were raised that the AA committee had not adequately addressed this issue.	Recommendation remains open. Awaiting response from AA committee.	HIGH (Sandra Wroblewski assigned)

20	7/28/97	ELAB recommends to NELAC that the issue of primacy State laboratories in accrediting non-primacy State laboratories be referred to the Accrediting Authority Committee for further consideration.		Completed. The NELAC Accrediting Authority Committee has implemented this recommendation.	COMPLETE
21	7/28/97	ELAB strongly recommends to NELAC a vote for adoption of the Standards with modifications as specified and passed by ELAB motions on July 28, 1997.		Complete. NELAC adopted the standards.	COMPLETE
22	7/28/97	ELAB recommends that EPA Program Offices become more active in NELAC and promulgate regulations that are consistent with the NELAC standards as appropriate.	Nancy Wentworth, co-chair of the EMMC Panel on Laboratory Accreditation, discussed the steps that are being taken within the Agency to obtain a consensus opinion. In a meeting on March 9, 1999, the EPA Acting Deputy Administrator Peter Robertson agreed to pursue this.	Recommendation remains open. ELAB sent a letter to the EMMC Policy Council Co-Chairs noting that NELAC is awaiting critical input from EPA Program Offices through EMMC. ELAB encourages the Agency to provide that input in writing as soon as possible. Awaiting response from EMMC Policy Council.	HIGH (Wilson Hershey assigned)

23	1/16/98	<p>ELAB recommends to NELAC that an advisory appendix be written that addresses the issue of due process for laboratories. This appendix must address the rights, responsibilities, and obligations of the laboratories and accrediting authorities. The discussion should include, but not be limited to:</p> <ul style="list-style-type: none"> S the right of the laboratory to see the audit report prior to action; S the right of the laboratory to privacy during review; S the right of the laboratory to appeal prior to suspension or revocation; and S the right of the laboratory to confidentiality. 	Recommendation remains open. Awaiting response from AP committee.		HIGH (Wilson Hershey assigned to contact NELAC to address this.)
24	1/16/98	ELAB strongly recommends to NELAC that, during consideration of inclusion of sampling into NELAC standards, all stakeholders be represented.	Recommendation remains open. Awaiting response from Field Measurements ad hoc committee.	This recommendation relates to 41 and will addressed there.	INACTIVE
25	1/16/98	ELAB recommends that NELAC invite the Federal Partners Committee to make a report at NELAC IV (June 28, 1998) on their intention to 1) participate in NELAC; b) continue their own programs; and c) to serve as accrediting authorities.		B. Dutrow made presentation at NELAC IV plenary session on Federal Partners progress.	COMPLETE

26	1/16/98	ELAB recommends that EPA report on the Agency's action regarding PBMS and how it relates to the Quality Systems Chapter.		Awaiting response from EMMC Panel on Laboratory Accreditation.	INACTIVE
27A	7/1/98	ELAB recommends that EPA continue the Office of Water streamlining effort as an intermediate step to PBMS.	EPA has decided to develop a formal PBMS program for the Office of Water, separate from the OW streamlining.	Recommendation remains open. Awaiting response from EMMC Policy Council.	MEDIUM
27B	7/1/98	ELAB recommends that a PBMS subcommittee be formed to develop and offer recommendations during NELAC IV [i] for integrating the development of NELAC and PBMS.	ELAB accepted on December 10, 1998, the report of the PBMS workgroup as a product of ELAB with the incorporation of previous findings and minor editorial changes. It was decided that a formal ELAB report will be sent by ELAB to EPA with an appropriate cover letter introducing the document and its issues. The PBMS working group report has been submitted to EPA's Acting Deputy Administrator Peter Robertson, during a meeting on March 9, 1999, at which time he agreed to address this issue with the EMMC Policy Council.	ELAB PBMS report on ELAB website.	COMPLETE

28	7/1/98	ELAB recommends that the NELAC Program Policy and Structure Committee review the structure of the AARB, consider expanding its charter to include an annual Management Systems Review of NELAP operations by an independent organization, include state members from the accrediting authorities, and address the timing of such reviews.		Recommendation remains open. Awaiting response from PPS committee.	MEDIUM
29	7/1/98	ELAB recommends that EPA and the Department of Transportation address the inconsistencies between the EPA preservation requirements and the DOT shipping requirements.	ELAB sent a letter to both EPA and DOT requesting prompt resolution to this impasse. In a meeting on January 11, 1999, the EMMC Policy Council Co-chair Noreen Noonan agreed to pursue this issue.	Response received from DOT stating that the shipping requirements will not be changed. Awaiting response from EMMC Policy Council.	HIGH (Wilson Hershey assigned)
30	7/1/98	ELAB recommends that the proposed changes to the NELAC standards be adopted in the voting session scheduled for July 2, 1998.		Changes adopted.	COMPLETE

31	7/1/98	ELAB recommends that a third-party assessor workgroup be formed to evaluate minimum credentials for third-party assessors, both individuals and organizations. The workgroup will also review NELAC Chapter 6 to determine if the criteria are sufficient for States to evaluate third party assessors and make recommendations for revisions if not.	A work group has been formed chaired by Sandra Wroblewski and Bill Kavanagh.	Awaiting product from work group.	HIGH (Sandra Wroblewski and Bill Kavanagh assigned)
32	7/1/98	ELAB recommends that the ELAB Laboratory Assessment workgroup recommendations on checklists be forwarded to the NELAC On-site Assessment Committee for their consideration		Awaiting response from OA committee. Jerry Parr revised report for ELAB review and submission to NELAC. Report approved as final ELAB report for forwarding to NELAC and OA committee 4/29/99.	HIGH (Jerry Parr assigned)
33	7/1/98	ELAB recommends that the NELAC Accrediting Authority Committee further define and address conflict of interest between public and private sector laboratories.		Awaiting response from AA committee. This issue will be covered in recommendation 23.	INACTIVE
34	7/1/98	ELAB recommends that the NELAC Accreditation Process committee develop an advisory appendix that addresses the rights, responsibilities, and obligations of laboratories and accrediting authorities.		Awaiting response from AP committee. Issue will be covered in recommendation 23.	INACTIVE

35	1/14/99	ELAB recommends that NELAC reach out to laboratory associations through its web page by providing relevant links and sample standard operating procedures, case histories, sample quality manuals, and work sheets to assist small laboratories.		Recommendation remains open. Awaiting response from Regulatory Coordination committee.	HIGH (Wilson Hershey to assign Gary Kramer)
36	1/14/99	ELAB will ensure a flow of information and guidance to the NELAC Committees by submitting significant information on to the NELAC Membership and Outreach Committee.		Recommendation remains open. Awaiting input from ELAB. W. Hershey to inform M&O committee of FL and KS websites to assist small labs.	INACTIVE
37	1/14/99	ELAB recommends that NELAC continue to ensure that the NELAC standards contain only essentials to achieve the desired data quality; and, ELAB will make small laboratory issues a standing agenda item for future ELAB meetings.		Recommendation remains open. Awaiting input from ELAB. ELAB continues to include small laboratory issues on agendas.	INACTIVE
38	1/14/99	ELAB recommends to NELAC that the NELAC Accreditation Process and Field Measurements Committees work together to develop a clear definition of critical terms (i.e., field laboratory, mobile laboratory, field measurement, and fixed laboratory) prior to defining the accreditation process for other than fixed laboratories; and, ELAB recommends to NELAC to exclude on-line monitors from its consideration.		Recommendation remains open. Awaiting response from AP and FM committees.	HIGH (Al Verstuyft assigned)

39	1/14/99	ELAB believes the current EPA proficiency testing program for water is unacceptably limited. ELAB recommends that EPA act quickly to broaden the availability of proficiency testing samples for matrices other than water (e.g. solid waste, air, tissue, etc.)		Recommendation remains open. Awaiting response from EMMC Policy Council	HIGH (Kathy Hillig assigned)
40	1/14/99	ELAB recommends to NELAC that a) the NELAC standards become effective and enforceable one year after adoption, and b) that for the first group of laboratories to be accredited under NELAC standards, the 1999 standards be used for compliance and that the related timelines for acceptance of applications be adjusted accordingly.		Recommendation remains open. Awaiting response from NELAC Board.	MEDIUM
41	12/10/98	ELAB recommends that work should forge on for field measurement standards. It was agreed that field sampling should be approached to determine the needs of stakeholders for standard-setting. ELAB recommends that the Field Measurements ad hoc committee compile the variability associated with field sampling, collect field sampling protocols, review ISO guides for approaches, consult stakeholders, and re-visit the needs of EPA/OAR on the matter of field sampling.		Recommendation remains open. Awaiting response from FM committee.	HIGH (Al Verstuyft assigned)

42	3/1/99	ELAB recommends to NELAC that the lab inspections be done according to NELAC standards and that the national database only track whether a lab is accredited and not have a separate category for interim status.	ELAB, at request of C. Batterton, NELAC BoD, considered the need for a new on-site related to the timing of the first Accrediting Authority recognitions in July 1999.	ELAB letter sent to NELAC, 3/25/99. Awaiting action by NELAC.	HIGH (Wilson Hershey assigned)
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